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10/578,216	05/03/2006	Kevin R. Lynch	00944-03	7580	
34444 INIVERSITY	7590 08/30/2007 OF VIRGINIA PATENT I	FOUNDATION	EXAMINER		
250 WEST MAIN STREET, SUITE 300			YOUNG, SHAWQUIA		
CHARLOTTE	SVILLE, VA 22902		ART UNIT	PAPER NUMBER	
			1626	•	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)			
Office Action Summary		10/578,216	LYNCH ET AL.			
		Examiner	Art Unit			
		Shawquia Young	1626			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHI WHIC - Exter after - If NO - Failu Any I	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication, operiod for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim till apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	I.  lely filed  the mailing date of this communication.  D (35 U.S.C. § 133).			
Status						
2a)□	Responsive to communication(s) filed on This action is <b>FINAL</b> . 2b) This Since this application is in condition for allower closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Dispositi	ion of Claims		•			
5) 6) 7)	Claim(s) 1-49 is/are pending in the application. 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) 1-49 are subject to restriction and/or expressions.	vn from consideration.				
Applicati	ion Papers					
10)	The specification is objected to by the Examine The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Examine	epted or b) objected to by the I drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).			
Priority (	under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
2)  Notice 3)  Infor	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Do 5) Notice of Informal P 6) Other:	ate			

#### **DETAILED ACTION**

Claims 1-49 are currently pending in this application.

#### Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

## Lack of Unity Requirement

Claims 1-49 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

(i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or

(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to the numerous variables in the claims, e.g. R<sup>16</sup>, R<sup>17</sup>, R<sup>15</sup>, R<sup>22</sup>, R<sup>23</sup>, R<sup>24</sup>, W, Y, Z, R<sub>3</sub>, R<sub>7</sub>, R<sub>8</sub>, R<sub>11</sub>, R<sub>15</sub>, etc. and their widely divergent meanings, a precise listing of inventive groups cannot be made. *The following groups are exemplary*:

**Group I** claim(s) 1-36 (in part), are drawn to a compound of the second formula represented in claim 1 wherein:  $R_7$  is NH;  $R_8$  is N;  $R_{25}$  is CH;  $R_{11}$  is selected from the group consisting of  $C_{5-12}$  alkyl,  $C_{5-12}$  alkenyl,  $C_{5-12}$  alkynyl,  $C_{5-12}$  alkoxy,  $(CH_2)_pO(CH_2)_q$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  cycloalkyl) $R_{20}$ ,  $C_{1-10}$  alkoxy( $C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-10}$  alkoxy( $C_{5-10}$  cycloalkyl) $R_{20}$ ;  $R_{29}$  is as defined in claim 1;  $R_3$  is selected from the group consisting of H,  $C_{1-6}$  alkyl,  $(C_{1-4})OH$ , and  $(C_{1-4}$  alkyl) $NH_2$ ;  $R_{23}$  is as defined in claim 1;  $R_{24}$  is selected from the group consisting of H, F and  $PO_3H_2$ ;  $R_{15}$  is  $-X-P=R_{12}(R_{30}R_{31})$ ;  $R_{12}$  is selected from the group consisting of O, NH and S; X is O; and  $R_{30}$  and  $R_{31}$  are independently selected from the group as defined in claim 1;  $R_{20}$  is H or  $C_{1-10}$  alkyl; m and y are integers independently ranging from 0 to 4; p and q are integers independently ranging from 1 to 10; n is an integer ranging from 0 to 10, classified in various subclasses in class 548.

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**Group II** claim(s) 1-36 (in part), are drawn to a compound of the second formula represented in claim 1 wherein:  $R_7$  is O  $R_8$  is N;  $R_{25}$  is N;  $R_{11}$  is selected from the group consisting of  $C_{5-12}$  alkyl,  $C_{5-12}$  alkenyl,  $C_{5-12}$  alkynyl,  $C_{5-12}$  alkoxy,  $(CH_2)_pO(CH_2)_q$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  cycloalkyl) $R_{20}$ ,  $C_{1-10}$  alkoxy( $C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  cycloalkyl) $R_{20}$ ;  $R_{29}$  is as defined in claim 1;  $R_3$  is selected from the group consisting of H,  $C_{1-6}$  alkyl,  $(C_{1-4})OH$ , and  $(C_{1-4}$  alkyl) $NH_2$ ;  $R_{23}$  is as defined in claim 1;  $R_{24}$  is selected from the group consisting of H, F and  $PO_3H_2$ ;  $R_{15}$  is  $-X-P=R_{12}(R_{30}R_{31})$ ;  $R_{12}$  is selected from the group consisting of O, NH and S; X is O; and  $R_{30}$  and  $R_{31}$  are independently selected from the group as defined in claim 1;  $R_{20}$  is H or  $C_{1-10}$  alkyl; m and y are integers independently ranging from 0 to 4; p and q are integers independently ranging from 1 to 10; n is an integer ranging from 0 to 10, classified in various subclasses in class 548.

**Group III** claim(s) 1-36 (in part), are drawn to a compound of the second formula represented in claim 1 wherein:  $R_7$  is S;  $R_8$  is N;  $R_{25}$  is N;  $R_{11}$  is selected from the group consisting of  $C_{5-12}$  alkyl,  $C_{5-12}$  alkenyl,  $C_{5-12}$  alkynyl,  $C_{5-12}$  alkoxy,  $(CH_2)_pO(CH_2)_q$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  cycloalkyl) $R_{20}$ ,  $C_{1-10}$  alkoxy( $C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-10}$  alkoxy( $C_{5-10}$  cycloalkyl) $R_{20}$ ;  $R_{29}$  is as defined in claim 1;  $R_3$  is selected from the group consisting of H,  $C_{1-6}$  alkyl,  $(C_{1-4})OH$ , and  $(C_{1-4}$  alkyl) $NH_2$ ;  $R_{23}$  is as defined in claim 1;  $R_{24}$  is selected from the group consisting of H, F and  $PO_3H_2$ ;  $R_{15}$  is  $-X-P=R_{12}(R_{30}R_{31})$ ;  $R_{12}$  is selected from the group consisting of O, NH and S; X is O; and  $R_{30}$  and  $R_{31}$  are independently selected from the group as defined in claim 1;  $R_{20}$  is H or  $C_{1-10}$  alkyl; m and y are integers independently ranging from 0 to 4; p and q are integers

independently ranging from 1 to 10; **n** is an integer ranging from 0 to 10, classified in various subclasses in class 548.

**Group IV** claim(s) 1-36 (in part), are drawn to a compound of the second formula represented in claim 1 wherein:  $R_7$  is N;  $R_8$  is O;  $R_{25}$  is O;  $R_{11}$  is selected from the group consisting of  $C_{5-12}$  alkyl,  $C_{5-12}$  alkenyl,  $C_{5-12}$  alkynyl,  $C_{5-12}$  alkoxy,  $(CH_2)_pO(CH_2)_q$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  cycloalkyl) $R_{20}$ ,  $C_{1-10}$  alkoxy( $C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  cycloalkyl) $R_{20}$ ;  $R_{29}$  is as defined in claim 1;  $R_3$  is selected from the group consisting of H,  $C_{1-6}$  alkyl,  $(C_{1-4})OH$ , and  $(C_{1-4}$  alkyl) $NH_2$ ;  $R_{23}$  is as defined in claim 1;  $R_{24}$  is selected from the group consisting of H, F and  $PO_3H_2$ ;  $R_{15}$  is  $-X-P=R_{12}(R_{30}R_{31})$ ;  $R_{12}$  is selected from the group consisting of O, NH and S; X is O; and  $R_{30}$  and  $R_{31}$  are independently selected from the group as defined in claim 1;  $R_{20}$  is H or  $C_{1-10}$  alkyl; m and m are integers independently ranging from 0 to 4; m and m are integers independently ranging from 1 to 10; m is an integer ranging from 0 to 10, classified in various subclasses in class 548.

**Group V** claim(s) 1-36 (in part), are drawn to a compound of the second formula represented in claim 1 wherein:  $R_7$  is N;  $R_8$  is CH;  $R_{25}$  is O;  $R_{11}$  is selected from the group consisting of  $C_{5-12}$  alkyl,  $C_{5-12}$  alkenyl,  $C_{5-12}$  alkynyl,  $C_{5-12}$  alkoxy,  $(CH_2)_pO(CH_2)_q$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  cycloalkyl) $R_{20}$ ,  $C_{1-10}$  alkoxy( $C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-10}$  alkoxy( $C_{5-10}$  cycloalkyl) $R_{20}$ ;  $R_{29}$  is as defined in claim 1;  $R_3$  is selected from the group consisting of H,  $C_{1-6}$  alkyl,  $(C_{1-4})OH$ , and  $(C_{1-4}$  alkyl) $NH_2$ ;  $R_{23}$  is as defined in claim 1;  $R_{24}$  is selected from the group consisting of H, F and  $PO_3H_2$ ;  $R_{15}$  is  $-X-P=R_{12}(R_{30}R_{31})$ ;  $R_{12}$  is selected from the group consisting of O, NH and S; X is O; and  $R_{30}$  and  $R_{31}$  are

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independently selected from the group as defined in claim 1;**R**<sub>20</sub> is H or C<sub>1-10</sub> alkyl; **m** and **y** are integers independently ranging from 0 to 4; **p** and **q** are integers independently ranging from 1 to 10; **n** is an integer ranging from 0 to 10, classified in various subclasses in class 548.

**Group VI** claim(s) 37-49 (in part), are drawn to a method of use for a compound of the second formula represented in claim 1 wherein:  $R_7$  is NH;  $R_8$  is N;  $R_{25}$  is CH;  $R_{11}$  is selected from the group consisting of  $C_{5-12}$  alkyl,  $C_{5-12}$  alkenyl,  $C_{5-12}$  alkynyl,  $C_{5-12}$  alkoxy,  $(CH_2)_pO(CH_2)_q$ ,  $C_{1-8}$  alkyl $(C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-8}$  alkyl $(C_{5-10}$  cycloalkyl) $R_{20}$ ,  $C_{1-10}$  alkoxy $(C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-10}$  alkoxy $(C_{5-10}$  cycloalkyl) $R_{20}$ ;  $R_{29}$  is as defined in claim 1;  $R_3$  is selected from the group consisting of H,  $C_{1-6}$  alkyl,  $(C_{1-4})OH$ , and  $(C_{1-4}$  alkyl)NH<sub>2</sub>;  $R_{23}$  is as defined in claim 1;  $R_{24}$  is selected from the group consisting of H, F and PO<sub>3</sub>H<sub>2</sub>;  $R_{15}$  is  $-X-P=R_{12}(R_{30}R_{31})$ ;  $R_{12}$  is selected from the group consisting of O, NH and S; X is O; and  $R_{30}$  and  $R_{31}$  are independently selected from the group as defined in claim 1;  $R_{20}$  is H or  $C_{1-10}$  alkyl; m and m are integers independently ranging from 0 to 4; m and m are integers independently ranging from 0 to 10, classified in various subclasses in class 514.

**Group VII** claim(s) 37-49 (in part), are drawn to a method of use for a compound of the second formula represented in claim 1 wherein:  $R_7$  is O  $R_8$  is N;  $R_{25}$  is N;  $R_{11}$  is selected from the group consisting of  $C_{5-12}$  alkyl,  $C_{5-12}$  alkenyl,  $C_{5-12}$  alkynyl,  $C_{5-12}$  alkoxy,  $(CH_2)_pO(CH_2)_q$ ,  $C_{1-8}$  alkyl $(C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-8}$  alkyl $(C_{5-10}$  cycloalkyl) $R_{20}$ ,  $C_{1-10}$  alkoxy $(C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-10}$  alkoxy $(C_{5-10}$  cycloalkyl) $R_{20}$ ;  $R_{29}$  is as defined in claim 1;  $R_3$  is selected from the group consisting of H,  $C_{1-6}$  alkyl,  $(C_{1-4})OH$ , and  $(C_{1-4}$  alkyl)NH<sub>2</sub>;  $R_{23}$  is as

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defined in claim 1;  $R_{24}$  is selected from the group consisting of H, F and  $PO_3H_2$ ;  $R_{15}$  is – X-P= $R_{12}(R_{30}R_{31})$ ;  $R_{12}$  is selected from the group consisting of O, NH and S; X is O; and  $R_{30}$  and  $R_{31}$  are independently selected from the group as defined in claim 1; $R_{20}$  is H or  $C_{1-10}$  alkyl;  $\mathbf{m}$  and  $\mathbf{y}$  are integers independently ranging from 0 to 4;  $\mathbf{p}$  and  $\mathbf{q}$  are integers independently ranging from 0 to 10, classified in various subclasses in class 514.

**Group VIII** claim(s) 37-49 (in part), are drawn to a method of use for a compound of the second formula represented in claim 1 wherein:  $R_7$  is S;  $R_8$  is N;  $R_{25}$  is N;  $R_{11}$  is selected from the group consisting of  $C_{5-12}$  alkyl,  $C_{5-12}$  alkenyl,  $C_{5-12}$  alkynyl,  $C_{5-12}$  alkoxy,  $(CH_2)_pO(CH_2)_q$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-8}$  alkyl( $C_{5-10}$  cycloalkyl) $R_{20}$ ,  $C_{1-10}$  alkoxy( $C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-10}$  alkoxy( $C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-10}$  alkoxy( $C_{5-10}$  cycloalkyl) $R_{20}$ ;  $R_{29}$  is as defined in claim 1;  $R_3$  is selected from the group consisting of H,  $C_{1-6}$  alkyl,  $(C_{1-4})OH$ , and  $(C_{1-4}$  alkyl) $NH_2$ ;  $R_{23}$  is as defined in claim 1;  $R_{24}$  is selected from the group consisting of H, F and  $PO_3H_2$ ;  $R_{15}$  is -  $X-P=R_{12}(R_{30}R_{31})$ ;  $R_{12}$  is selected from the group consisting of O, NH and S; X is O; and  $R_{30}$  and  $R_{31}$  are independently selected from the group as defined in claim 1;  $R_{20}$  is H or  $C_{1-10}$  alkyl;  $\mathbf{m}$  and  $\mathbf{y}$  are integers independently ranging from 0 to 4;  $\mathbf{p}$  and  $\mathbf{q}$  are integers independently ranging from 0 to 10, classified in various subclasses in class 514.

**Group IX** claim(s) 37-49 (in part), are drawn to a method of use for a compound of the second formula represented in claim 1 wherein:  $\mathbf{R}_7$  is N;  $\mathbf{R}_8$  is O;  $\mathbf{R}_{25}$  is O;  $\mathbf{R}_{11}$  is selected from the group consisting of  $\mathbf{C}_{5-12}$  alkyl,  $\mathbf{C}_{5-12}$  alkenyl,  $\mathbf{C}_{5-12}$  alkynyl,  $\mathbf{C}_{5-12}$  alkoxy,  $(\mathbf{CH}_2)_p \mathbf{O}(\mathbf{CH}_2)_q$ ,  $\mathbf{C}_{1-8}$  alkyl( $\mathbf{C}_{5-10}$  aryl) $\mathbf{R}_{20}$ ,  $\mathbf{C}_{1-8}$  alkyl( $\mathbf{C}_{5-10}$  cycloalkyl) $\mathbf{R}_{20}$ ,  $\mathbf{C}_{1-10}$  alkoxy( $\mathbf{C}_{5-10}$ 

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aryl) $R_{20}$ ,  $C_{1-10}$  alkoxy( $C_{5-10}$  cycloalkyl) $R_{20}$ ;  $R_{29}$  is as defined in claim 1;  $R_3$  is selected from the group consisting of H,  $C_{1-6}$  alkyl, ( $C_{1-4}$ )OH, and ( $C_{1-4}$  alkyl)NH<sub>2</sub>;  $R_{23}$  is as defined in claim 1;  $R_{24}$  is selected from the group consisting of H, F and PO<sub>3</sub>H<sub>2</sub>;  $R_{15}$  is – X-P= $R_{12}$ ( $R_{30}R_{31}$ );  $R_{12}$  is selected from the group consisting of O, NH and S; X is O; and  $R_{30}$  and  $R_{31}$  are independently selected from the group as defined in claim 1; $R_{20}$  is H or  $C_{1-10}$  alkyl; m and y are integers independently ranging from 0 to 4; p and q are integers independently ranging from 0 to 10, classified in various subclasses in class 514.

**Group X** claim(s) 37-49 (in part), are drawn to a method of use for a compound of the second formula represented in claim 1 wherein:  $R_7$  is N;  $R_8$  is CH;  $R_{25}$  is O;  $R_{11}$  is selected from the group consisting of  $C_{5-12}$  alkyl,  $C_{5-12}$  alkenyl,  $C_{5-12}$  alkynyl,  $C_{5-12}$  alkoxy,  $(CH_2)_pO(CH_2)_q$ ,  $C_{1-8}$  alkyl $(C_{5-10}$  aryl) $R_{20}$ ,  $C_{1-8}$  alkyl $(C_{5-10}$  cycloalkyl) $R_{20}$ ,  $C_{1-10}$  alkoxy $(C_{5-10}$  alkoxy) $(C_{5-10}$  cycloalkyl) $R_{20}$ ;  $R_{29}$  is as defined in claim 1;  $R_3$  is selected from the group consisting of H,  $C_{1-6}$  alkyl,  $(C_{1-4})OH$ , and  $(C_{1-4}$  alkyl) $NH_2$ ;  $R_{23}$  is as defined in claim 1;  $R_{24}$  is selected from the group consisting of H, F and  $PO_3H_2$ ;  $R_{15}$  is -  $X-P=R_{12}(R_{30}R_{31})$ ;  $R_{12}$  is selected from the group consisting of O, NH and S; X is O; and  $R_{30}$  and  $R_{31}$  are independently selected from the group as defined in claim 1;  $R_{20}$  is H or  $C_{1-10}$  alkyl;  $R_{10}$  and  $R_{10}$  are integers independently ranging from 0 to 4;  $R_{10}$  and  $R_{10}$  are integers independently ranging from 0 to 10, classified in various subclasses in class 514.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to

elect a single invention to which the claims must be restricted. Again, this list is not exhausted, as it would be impossible under the time constraints due to the sheer volume of subject matter instantly claimed. Therefore, applicant may choose to elect a single invention by identifying another specific embodiment not listed in the exemplary groups of the invention and examiner will endeavor to group the same. If applicant is unable to elect a single invention, applicant may instead choose to elect a specific compound and examiner will attempt to group it. The claims herein lack unity of invention under PCT Rule 13.1 and 13.2 since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art (See, WO 02/076995, for example). The

$$R_{29}$$
 (CH<sub>2</sub>)<sub>m</sub>  $R_{7}$   $R_{8}$  (CH<sub>2</sub>)<sub>y</sub>  $CR_{15}$   $R_{11}$   $R_{11}$   $R_{29}$   $R_{12}$   $R_{15}$   $R_{11}$   $R_{11}$   $R_{12}$   $R_{13}$   $R_{12}$   $R_{13}$   $R_{14}$ 

compounds claimed contain

does not define a contribution over the prior art. The compounds vary in classification and when taken as a whole result in vastly different compounds. Accordingly, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter imposes a burden on any examination of the claimed subject matter.

### Advisory of Rejoinder

The following is a recitation of M.P.E.P. 821.04, Rejoinder:

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP

§ 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be

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allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101,102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action. Form paragraphs 8.42 through 8.44 should be used to notify applicant of the rejoinder of process claims which depend from or otherwise include all the limitations of an allowable product claim.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)" (1184 TMOG 86(March 26, 1996)):

"However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with M.P.EP 821.04 and In re Ochiai, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**.

Applicant is advised that the reply to this requirement to be complete must

include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

# Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 6:30 AM-3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shawqua Young
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

Joseph McKane Supervisory Patent Examiner Art Unit 1626, Group 1620 Technology Center 1600

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